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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,214	02/11/2002	Lennart Hansson	HANSSON 3A	9275

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EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,214	HANSSON ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *3 and 36-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06/05/2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *12* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-28 in Paper No. 11 is acknowledged. Applicant further elected SEQ ID NO:6, with traverse, in response to the sequence restriction. While the examiner maintains that Groups I and II are patentably distinct, it has been determined that searching Groups I and II does not require undue burden on the part of the examiner, and they will be rejoined. Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Claims 36-58 are also withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction and species (election) requirement in Paper No. 11.

The traversal of the restriction requirement is on the ground(s) that Groups II-IV are dependent upon patentable claims of Group I. This is not found persuasive because no claim of Group I been deemed patentable.

The traversal of the species election requirement is on the ground(s) that a generic claim is allowable. This is not found persuasive because no claim of Group I been deemed allowable.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-58 are pending, however, claims 3 and 36-58 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 11. Claims 1,2, and 4-35 are under current examination.

Sequence Compliance

Applicant argues that the degenerate sequences listed in the specification and claims as recited in section 7 of the Notice to Comply issued with the Restriction mailed 12/09/2002, paper number 10, do not require individual SEQ ID NO.s for each individual sequence embodied by

the generic sequences. Applicant's arguments are found persuasive and the issue of sequence compliance has been withdrawn. However, a sequence identifier (SEQ ID NO:15) is required with the sequence listed in claim 4.

Specification

The disclosure is objected to because of the following informalities:

Page 18, line 30 refers to amino acid no. –7 through no. 224 of SEQ ID NO:2, however, SQ ID NO:2 does not comprise an amino acid no. –7. Clarification of what is intended is needed.

In the LEGEND TO FIGURES, page 22, "A:" (line 13) should read "Figure 3A". "B:" (line 19) should read "Figure 3B". "A:" (line 32) should read "Figure 4A". On page 23, "B:" (line 1) should read "Figure 4B".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,2, and 4-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at

1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

While the specification provides adequate written description for transgenic mice comprising the human SCCE gene wherein the transgene encodes a protein with the amino acid sequence of SEQ ID NO:2, or wherein the transgene comprises SEQ ID NO:1, the specification fails to describe any nucleic acid fragments encoding at least a significant part of SCCE, as encompassed in the claims with particularity to indicate that Applicants had possession of the claimed invention. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art **as of Applicants effective filing date**. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case, the claimed embodiment of any SCCE nucleic acid fragments lacks a written description. The specification fails to describe which nucleic acid fragments of SCCE or SEQ ID NO:2 fall into this genus when constructed and used as claimed. The skilled artisan cannot envision all such fragments of SCCE transgenes, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, as no SCCE nucleic acid fragments were described, no such nucleic acid fragments meet the written description provision of 35 U.S.C. § 112.

The specification fails to provide adequate written description of the non-human mammals or mammalian embryos as claimed in claims 21 and 22. Claims 21 and 22 recite that the transgenic mammals exhibit a predisposition for cancer. However, the only phenotype described for the transgenic mammals in question are skin abnormalities. Therefore, as a predisposition to cancer was not described, the written description provision of 35 U.S.C. § 112 was not met for claims 21 and 22.

The specification does not provide adequate written description for the claimed mammalian embryos presenting any phenotype claimed in claims 21-28. The claimed phenotypes include: an abnormal skin phenotype (claims 20 and 21), predisposition for cancer or ovarian cancer (claims 21 and 22), an abnormal skin phenotype resembling skin disease (claim 23), epidermal hyperkeratosis, achantosis, epidermal and/or dermal inflammation and/or pruritus (claims 24 and 25), an abnormal skin phenotype resembling psoriasis (claim 26) or resembling chronic atopic dermatitis or chronic eczema (claim 27) or resembling inherited skin diseases with epidermal hyperkeratosis (claim 28). The specification teaches transgenic mice with the phenotypes claimed but does not teach any phenotype in mammalian embryos (page 32, lines 21-39 through page 33 lines 1-15). Therefore, as an abnormal phenotype was not described for the claimed transgenic mammalian embryos, the written description provision of 35 U.S.C. § 112 was not met for claims 21-28.

Applicant is reminded that *Vas -Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1,2 and 4-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse comprising a transgene comprising SEQ ID NO:1, or encoding SEQ ID NO:2, operably linked to the SV40 promoter wherein said mouse displays epidermal hyperplasia and hyperkeratosis and a mild cellular inflammatory reaction of the skin, does not reasonably provide enablement for any non human transgenic mammal or mammalian embryo comprising a nucleic acid comprising any significant part of SEQ ID NO:1 or encoding any significant part of SEQ ID NO:2 or encoding a protein with at least 75% sequence identity to SEQ ID NO:2, operably linked to any promoter with activity in skin wherein said animal has any phenotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims are directed to a non human transgenic mammal or mammalian embryo comprising a nucleic acid encoding any significant part of an SCCE or a variant thereof operably linked to a promoter that drives expression in skin (claims 1,2,5-8,16-18,29,30 and 32-35) wherein the mammal exhibits an abnormal (claim 19) skin (claim 20, 23-28 and 31) phenotype or exhibits a predisposition for cancer (claims 21, 22 and 31). Claims 4,10-13 are directed to the transgenic mammal or mammalian embryo of claim 1 wherein a significant part of the transgene encodes a protein with at least 75% amino acid identity to SEQ ID NO:2 wherein said protein contains SEQ ID NO:6 (claim 4). Claims 9,14 and 15 are directed to the transgenic mammal or mammalian embryo of claim 1 wherein the nucleic acid comprises SEQ ID NO:1.

1) The specification fails to enable generating any species of non human transgenic mammal or mammalian embryo comprising a transgene comprising a gene encoding SEQ ID NO:2 operably linked to any promoter that drives expression in skin.

As the current state of the transgenic animal research stands, there are several significant limitations to applying transgenic technology to animals to different species. Longer gestation times, reduced litter sizes, number of fertilized eggs required for microinjection and relatively low efficiency of gene integration and method of introduction of transgenes are a few examples of such limitations. Investigators observed 5-70 fold lower yields of a recombinant protein in transgenic mice when they used a construct designed for expression in sheep (Mullins, 1993, Hypertension, Vol. 22, pages 630-633; specifically page 632, col 1, 4th paragraph, lines 1-12). Variation in expression levels between different cell lines and species may be attributed to host genetic background, the site of chromosomal insertion and absence of specific transcription factors.

In a more recent assessment of the transgenic technology, Cameron (1997, Molecular Biotechnology Vol. 7, pages 253-265) noted, " Well regulated transgene expression is the key to successful transgenic work, but all too often experiments are blighted by poor levels or the complete absence of expression, as well as less common problems, such as leaky expression in nontargeted tissues. A feature common to many transgenic experiments is the unpredictable transgenic lines produced with the same construct frequently displaying different levels of expression. Further, expression levels do not correlate with the number of transgene copies integrated. Such copy- number-independent expression patterns emphasize the influence of surrounding chromatin on the transgene" (see page 256, section 4 on transgene regulation and expression).

Several animal models of human diseases have relied on transgenic rats when the development of mouse models was not feasible. For example, Hammer (1990, Cell Vol. 63, pages 1099-1112) generated both transgenic mice and rats expressing human HLA-b27 gene and beta-2 microglobulin. Although, both the transgenic animals bearing HLA-27 gene expressed the gene, transgenic mice did not show any HLA-2 associated disease whereas the transgenic rats demonstrated most of the HLA-B27 related diseases (refer to page 1099, column 2, lines 20-28). This demonstrates that the integration of a transgene into alternative species may result in widely different phenotypic responses. Additionally, promoters and enhancer elements may not function in all the species because they may require specific cellular factors. Mullins (1996, J. Clin. Invest. Vol. 98, pages S37-S40) disclosed that the use of nonmurine species for transgenesis will continue to reflect the suitability of a particular species for the specific questions being addressed, bearing in mind that a given construct may react very differently from one species to another. Additionally, promoters and enhancer elements may not function in all species because they may require specific cellular factors. Therefore, it was unpredictable at the time of filing what gene of interest, promoter, enhancer, coding, or non-coding sequences present in the transgene construct, site of integration, or species of animal used, were required to make a transgenic non-human mammal of interest.

The specification teaches a transgenic mouse comprising a transgene encoding SEQ ID NO: 2 operably linked to an SV40 promoter. The specification does not teach generating any other species of transgenic, eukaryotic animal using any promoter other than the SV40 promoter wherein the animal exhibits a phenotype. The specification does not provide any guidance as to whether a given promoter used for expressing an exogenous gene in one animal would have been functional in other animals. Furthermore, if the promoter were active in other

species, the level of the transgene product produced may not have been sufficient to produce a certain, desired phenotype. If not, what steps would have been taken to address this issue?

While one of skill in the art has many skin specific promoters available to drive expression of a gene in the skin, the specification teaches that not all skin promoters successfully drive expression of a gene encoding SEQ ID NO:2 to the skin as expected (page 10, lines 26-34). In fact, the ubiquitous SV40 promoter that was not expected to have skin-specific activity, resulted in significantly higher levels of transgene expression in the suprabasal and more superficial layers of the skin than in other tissues. As the inventors note, this is indicative of unidentified control elements within the transgene (page 11, lines 34-36). Furthermore, it is not clear whether the transgene described in the specification will give the desired phenotype when used to generate other species of transgenic animals because the gene product and promoter may have different, unpredictable activities in species other mice.

Due to the unpredictability set forth by the art of making transgenic animals and because the specification fails to provide any guidance as to how an artisan would have dealt with the art recognized limitations of the method for making any and all transgenic animals, the creation of any and all non-mouse animals, or mice with any promoter other than SV40 promoter operably linked to an SCCE gene, would have necessitated undue experimentation on the part of an artisan.

2) The specification does not enable any nucleotide sequences comprising at least a significant part of a nucleotide sequence encoding for an SCCE or a "variant thereof" (claims 1,2 and 4-25) or encoding a protein with an amino acid sequence which has a sequence identity of at least 75% to SEQ ID NO:2 (claim 4) as broadly claimed. The specification defines "at least a significant part of a nucleotide sequence coding for SCCE" as encoding a polypeptide having at least a part of the amino acid sequence encoding a polypeptide having at least part of SEQ ID

NO:2 and preferably resulting in an abnormal phenotype (page 16, lines 26-29). The specification fails to describe which nucleic acid fragments of SCCE fall into this genus when constructed and used as claimed. The specification discloses that "a significant part" means a nucleotide encoding at least 50 amino acids (page 17, lines 2-3), however, the specification does not support or show any basis for this number. The specification defines the term "SCCE variant" as "not having exactly the amino acid sequence shown in SEQ ID NO:2, it may e.g. be a SCCE protease from another species...comprising a part of SEQ ID NO:2" that "will generally react" with antibodies designed to react with human SCCE and will have significant "SCCE activity" (page 13, lines 27-35). The specification does not teach, and it was not obvious to one skilled in the art at the time the invention was made how to predict, which regions "at least a significant part" of SCCE or what embodiments of the claimed homologous sequences encode the activity that results in the desired phenotype. The skilled artisan cannot envision all such fragments of SCCE transgenes.

The specification notes that it 'maybe even necessary" to include intron sequences when preparing a nucleotide sequence for the claimed transgenic (page 16, lines 30-31). However the specification does not teach which intron sequences and teaches that "It is likely that not all of the intron sequences are necessary and that intron sequences from SCCE from other species or intron sequences from genes coding for other proteins may also be suitable...." (page 16, lines 34-36). The specification does not provide any guidance as to how one would determine what intron sequences may be necessary or where they should be placed within the transgene to result in a functional transgene.

The lack of abnormal phenotype in mice comprising a transgene encoding human SCCE operably linked to the skin-specific keratin 14 promoter and in 2 lower-expressing lines of mice with the transgene encoding human SCCE operably linked to the SV40 could be the result of

lower activity of the human SCCE protease in mice. Thus, it is conceivable that any alterations in sequence from the endogenous SCCE gene will reduce the efficiency of obtaining a transgenic animal with the desired phenotype due to insufficient activity of transgene product. Without knowing where the active domains within the SCCE protein are located and which residues are essential for domain activity, it is not possible to conceive which amino acids must be present and which can be altered or deleted while retaining the desired SCCE activity.

Thus, in light of the support given in the specification, it would require one of skill in the art undue experimentation to determine which nucleic acids encompassed by the claims would result in a transgenic mammal having the desired phenotype.

3) The specification does not enable making and/or using a non human transgenic mammal or mammalian embryo comprising a nucleic acid comprising at least a significant part of a nucleotide sequence encoding an SCCE or encoding a protein with at least 75% amino acid identity with SEQ ID NO:2, that does not have a phenotype. Claims 1,2, and 4-19 encompass a non human transgenic mammal or mammalian embryo with a transgene insertion that causes any phenotype, including a wild-type phenotype (claims 1,2 and 4-18). Claims 21 and 22 are drawn said transgenic mammal or mammalian embryo wherein the mammal exhibits a predisposition for cancer. The specification does not provide support for this claimed phenotype. The state of the art at the time the invention was made was that endogenous SCCE is overexpressed in naturally occurring ovarian cancers (Tanimoto, H., 1997, Proc. Amer. Assoc. For Cancer Res, Vol. 38, page 413, Abstract # 2765 and Tanimoto, 1999, Cancer, Vol. 86, pages 2074-82); however, there was no evidence that overexpression of SCCE alone will cause ovarian cancer, or tumor metastasis, in an animal to serve as a disease model. Furthermore, and as stated above, the state of the art was that the phenotype of a transgenic mouse is unpredictable. Thus, it would require one of skill in the art to perform undue experimentation to

determine how to generate a transgenic mammal or mammalian embryo comprising a nucleic acid comprising at least a significant part of a nucleotide sequence encoding an SCCE or encoding a protein with at least 75% amino acid identity with SEQ ID NO:2 such that a predetermined, desired and useful phenotype is obtained.

4) The specification fails to enable making a transgenic mammalian embryo having integrated within its genome a nucleic acid comprising at least a significant part of a nucleotide sequence encoding an SCCE or encoding a protein with at least 75% amino acid identity with SEQ ID NO:2 wherein said embryo exhibits an abnormal skin phenotype (claims 20 and 21), predisposition for cancer or ovarian cancer (claims 21 and 22), an abnormal skin phenotype resembling skin disease (claim 23), epidermal hyperkeratosis, achantosis, epidermal and/or dermal inflammation and/or pruritus (claims 24 and 25), an abnormal skin phenotype resembling psoriasis (claim 26) or resembling chronic atopic dermatitis or chronic eczema (claim 27) or resembling inherited skin diseases with epidermal hyperkeratosis (claim 28). The specification teaches transgenic mice with the phenotypes claimed but does not teach any phenotype in mammalian embryos (page 32, lines 21-39 through page 33 lines 1-15). In fact, an abnormal phenotype was not noted until mice were several weeks of age. Because obvious abnormalities in skin phenotype are not apparent before several weeks of age in postnatal mice, there is no reason to believe that embryos would present the phenotypes claimed. The specification and the art at the time of filing did not teach how to generate the claimed transgenic mammalian embryo that exhibits the phenotypes claimed. Therefore, it would require the skilled artisan undue experimentation to determine how to generate the mammalian embryo claimed in claims 20-28.

Therefore, in view of the quantity of experimentation necessary to determine the parameters listed above, the lack of direction and/or guidance provided by the specification, the

unpredictability of phenotype in transgenic mice, and the breadth of the claims, it would have required undue experimentation for one skilled in the art to make and use the claimed invention with a reasonable expectation of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8,11,14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Markush group of claim 8 is improper as it contains only one member.

Claim 11 is unclear because it refers to amino acid no. –7 of SEQ ID NO:2 (line 2). It is not known what amino acid is being referred to. The amino acid sequence of SEQ ID NO:2 begins with amino acid no. 1.

Claims 14 and 15 recite the limitation "the DNA sequence" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claim. Parent claim 1 refers to 2 distinct "nucleotide sequence"s (lines 2 and 3). It is assumed that "the DNA sequence" of claims 14 and 15 refers to the term "nucleotide sequence" in claim 1 but it is not clear which one. Claims 14 and 15 require clear antecedent basis.

Conclusion

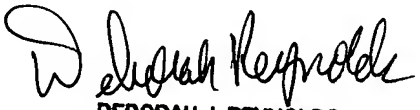
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner



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